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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,685	06/16/2000	Kieran P. J. Murphy	8627/405	2321

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EXAMINER

ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/594,685	Applicant(s) MIRPHY, KIERAN P. J.	
	Examiner Eduardo C. Robert	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 22, line 1, “wherein the vertebroplasty injection components comprise: a vertebroplasty needle”, is indefinite because it is unclear if the components are a combination of all the components, in combination, of the first and second tray, or if each tray, i.e. first and second, includes the components listed in claim 22.

Claim 23 has a problem similar to the one of claim 22.

It is noted that for examination purposes claim 22, would be considered as each tray including all the components listed in claim 22. Claim 23 would be considered in a similar fashion, e.g. each tray including all the components listed in claim 23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus, et al.

Lazarus, et al. disclose a kit 10 comprising a first tray 10a of components and a second tray 10b of components. The first and second tray are individually assembled and packaged and are kept sterile until use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagley (U.S. Patent No. 6,158,437 cited on PTO-892, paper no. 9).

Vagley discloses a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67). Vagley further discloses that the tray can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instrument to the surgeon (see col. 5, lines 40-50). Vagley define a surgical procedure as "a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive." (see col. 3, lines 5-10). Thus, it would have been obvious to one skill in the art at the time the

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invention was made to place specific tools, such as local anesthesia, anesthesia aspiration syringe; anesthesia aspiration needle; anesthesia injection needle; liquid monomer; monomer aspiration needle; monomer aspiration syringe; mixing bowl; mixing spatula; polymer powder; opacifier; scalpel; vertebroplasty needle, etc., need in a tray to cater to the preference of a specific surgeon during a specific procedure.

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagley (U.S. Patent No. 6,158,437 cited on PTO-892, paper no. 9) and Shanley, et al.; Macleod, et al.; Smith, et al.; Arlers; Racz; Jiang, et al.; Singer; Draenert; Haynie; Hertzman, et al.; and Baker are cited as evidence.

Vagley discloses a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67). Vagley further discloses that the tray can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instrument to the surgeon (see col. 5, lines 40-50). Vagley define a surgical procedure as “a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive.” (see col. 3, lines 5-10). Shanley, et al. disclose that kits or tray can include a local anesthesia injection needle 6. Macleod, et al. disclose that kits or tray can include a local anesthesia compound. Smith, et al. disclose a aspiration syringe for fluids (see col. 9, lines 9-11). Arlers discloses another aspiration syringe. Racz discloses an aspiration needle for fluids. Jiang, et al. disclose

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that liquid monomers can be on a kit or tray. Singer discloses another aspiration needle. Draenert discloses a mixing bowl and polymeric powder. Haynie discloses that a tray or kit can have a mixing spatula. Hertzman, et al. disclose that a tray or kit can include a scalpel. Baker discloses that a tray or kit can include opacifier. Thus, it would have been obvious to one skill in the art at the time the invention was made to place specific tools, such as local anesthesia, anesthesia aspiration syringe; anesthesia aspiration needle; anesthesia injection needle; liquid monomer; monomer aspiration needle; monomer aspiration syringe; mixing bowl; mixing spatula; polymer powder; opacifier; scalpel; vertebroplasty needle, etc., need in a tray to cater to the preference of a specific surgeon during a specific procedure.

Response to Arguments

Applicant's arguments filed on July 27, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that Lazarus does not have vertebroplasty injection components in either tray, it is noted that Lazarus's tray 10b includes a syringe 36 and needle 38 and they are capable of being used in a spinal surgical procedure, e.g. for injecting anesthesia. Lazarus's tray 10a includes a cannula for injecting and/or aspirating fluid and it is capable of being used in a spinal surgical procedure, e.g. for injecting or aspirating nucleus pulposus. Thus, it is clear that each tray include a injection component and they can perform a function in spinal surgery if one so desire. **Furthermore, with regard to the functional language "vertebroplasty", it is noted the manner in which a device is intended to be employed does**

not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In response to the Declaration filed on July 27, 2004 under 37 CFR 1.132, it is noted that the Declaration is insufficient to overcome the rejection of claims 1-21 based as set forth in the last Office action and this Office action because: the declaration is directed to an opinion from applicant and not to evidence. It is noted that in assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established (i.e. the ability of the different components to perform a function), the strength of any opposing evidence (i.e. no "evidence" has been presented with the declaration), the interest of the expert in the outcome of the case (i.e. the expert which in this case is the applicant has a 100 percent interest in the outcome of the case), and the presence or absence of factual support for the expert's opinion (i.e. no facts are presented to support the expert's opinion). *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). Factually based expert opinions on the level of ordinary skill in the art are sufficient to rebut the prima facie case of obviousness. *In re Oelrich*, 579 F.2d 86, 198 USPQ 210 (CCPA 1978). In the Declaration filed on July 27, 2004, no "facts" are present to support applicant's opinion. It is noted that "facts" are events, acts or occurrences which have actually taken place. Thus, the Declaration has been considered, however, it is not persuasive to overcome the art of record.

Furthermore, the examiner would like to point out another example of why the Declaration is not persuasive. For example, in the Declaration filed on July 24, 2004, the expert, i.e. the applicant of the current application, states that the Lazarus's syringe and needle are

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“NOT” vertebroplasty injection components, but the expert agrees that the Lazarus’s syringe and needle are capable of injecting anesthetic, including doing so into the spine, and that theses are general surgical apparatuses rather than vertebroplasty injection components. However, in applicants specification and claims, a local anaesthesia injection needle, which according to the declaration is a “genral surgical apparatus”, is considered a vertebroplasty injection components (see for example claim 22). Thus, clearly applicant is contradicting himself.

Also, in response to applicant’s argument in the declaration about that Lazarus’s and bone-cement injection needles, the limitations on which the Applicant relies (i.e., bone-cement injection needles) are not stated in the claims 17-19. Therefore, it is irrelevant whether the reference includes those features or not.

In response to applicant’s argumen in the declaration t that the Lazarus’s cannula is not a vertebroplasty injection component, it is noted that the cannula clearly, if one so desired, has the ability to perform the function of injection or aspirate as an injection or aspiration needle.

Furthermore, **it is noted the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).** In the current case Lazarus’s clearly has the structure recited in the claims, i.e. a first tray of components, a second tray of components and the first and second trays are individually assembled and packaged and kept sterile until use.

Furthermore, the declaration filed by applicant did not provide any evidence to prove that the structure of the device of Lazarus is incapable of performing the functions.

In response to applicant's argument about claim 17 and the recitation of "performing a first vertebroplasty injection through a first pedicle of a vertebral body" and "performing a second vertebroplasty injection through a second pedicle of said vertebral body" in the declaration, it is noted that claim 17 is an apparatus claim and not a method claim. Furthermore, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). The manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In response to applicant's argument in the declaration that Vagley disclose a rhinoplasty kit for plastic surgery and that none of the Vagley's components can be used for vertebroplasty, it is noted that in a piecemeal analysis of the reference, one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references. Furthermore, the examiner would like to point out that Vagley not only discloses a rhinoplasty kit. He further a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67) and he further discloses that the tray **can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery the correct instrument to the surgeon (see col. 5, lines 40-50).** Vagley define a surgical procedure as "a

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procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive” (see col. 3, lines 5-10).

In response to applicant's argument that the Examiner has not addressed applicant's argument of the Appeal Brief that "the Examiner has used Appellant's claims as a shopping list to find a patent that teaches each element in the combination, but has not cited or applied a reference that teaches the *combination* itself", it is noted that applicant's argument of the Appeal Brief were considered but were MOOT in view of the new ground(s) of rejection (as clearly stated in the last office action mailed on March 24, 2004). However, the examiner would like to point out that the rejections to the claims which include a "shopping list", as stated by applicant, are obviousness type of rejection not an anticipation rejection, thus if the examiner would have found the "*combination*" of elements itself, he would have done a 35 U.S.C. 102, anticipation rejection.

In response to applicant's argument that Vagley is a worse reference than Folkman, the examiner is not going to argue if Vagley is worse or better. The examiner only would like to point out that Vagley clearly teaches that to place specific tools, such as the ones disclosed in the claims and which applicant has clearly stated in the specification are known (see applicant's specification page 5, lines 14-15), need to perform a any particular surgical procedure is obvious in order to cater to the preference of a specific surgeon during a specific procedure (applicant's attention is directed to the rejection under 35 U.S.C. 103 under Vagley, for claims 1-16, 20, and 21).

Allowable Subject Matter

Claims 22 and 23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

The insertion of new claims 22 and 23 required the new ground of rejection, i.e. 35 U.S.C. 112, second paragraph, rejection (set forth above).

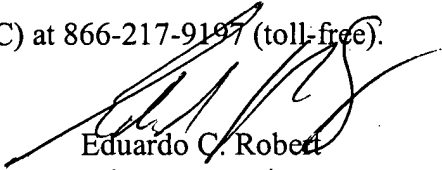
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.